EPA Reg. No. 83558-34



Makhteshim Agan of North America, Inc.

February 28, 2011

Document Processing Desk (FPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attn: Venus Eagle (PM #1) / Insecticide Rodenticide Branch

Registration Division Phone: 703-308-8045

Re: Imidacloprid Technical Insecticide - EPA Reg. No. 83558-34

Submission of Final Printed Labeling

Dear Ms. Eagle,

Celsius Property B.V., Amsterdam (NL) c/o Makhteshim Agan of North America, Inc. is submitted final printed labeling for the above referenced product in response to EPA's letter dated 02-17-2011.

In support of this submission, the following documents are attached:

- Application for Pesticide Registration (EPA Form 8570-1)
- Two copies of final printed labeling

Should you have any questions about this application, please contact me at 919-256-9315 or e-mail at jyentel@manainc.com.

Sincerely,

genuf gentel
Jennifer Yentel

Regulatory Specialist

Enclosure

·	· ·					(r'		Print Form	
Please read instructions on re	verse before complet	ing form.			Form Appr	oved.	UMB No. 20	70-0060		
United States Environmental Protection Age Washington, DC 20460			_	ncy		×	Registra Amendr Other		OPP Identifier Number	
		Application	n for E	Postici	do Con		, — , -			
1 Company Bradust Number		Application	101 7		Product Man		!	12.0-	oposed Classification	
1. Compeny/Product Number 83558-34				Venus				1_	, —	
4. Company/Product (Name) Imidacloprid Technical				PM#				٦Ľ	None Restricted	
5. Name and Address of Appli Celsius Property B.V., Ams c/o MANA, 4515 Falls of N Raleigh, NC 27609	sterdam (NL)	de)	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name						mposition and labeling	
		**************************************	Sect	tion -	J					
Amendment - Explain I Resubmission in respo	nse to Agency letter	dated		× - [Final printed Agency lett *Me Too* // Other - Exp	or dat Applic	etion.	to 02-1	17-2011	
Explanation: Use additions	nege(e) if necessary	/. (For easting	n I end Se	ction II.)						
Submission of Final Printed	d Label in response	to EPA's lett	er dated	02-17-2	011.					
			Sect	ion - l	11					
1. Material This Product Will I	Be Packaged in:									
Child-Resistant Packaging	Unit Packaging		Water	Soluble F	ackeging		2. Type of	•		
Yes	Yes			Yee			 x	Metal Plastic		
× N°	× No		<u> ×</u>	No]	Glass		
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	if "Yes Packag		No, per containe	r		Paper Other (S	Specify)	
3. Location of Net Contents In	nformation entainer	4. Size(e) Re	teil Contei	ner		5. Lo			ons opanying product	
6. Manner in Which Label is A	Affixed to Product	Lithog Paper Steno	raph glued lled		X Othe	r <u>sel</u>	f-adhesive			
				ion - I	V		-			
1. Contect Point (Complete in	tems directly below fo	or identification	on of indivi	idual to b	e contacted,	H nec	essery, to pr	ocess this	application.)	
Name Jennifer Yentel				Dogulaton, Specialist			•	elaphone No. (Include Area Code) 919-256-9315		
I certify that the etatem I acknowledge that any both under applicable is							6. Date Application Received (Stemped)			
2. Signature Glumsfe	yestd_		3. Title Regulate	ory Spec	tialist			4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4	(
4. Typed Name	<u> </u>		5, Date					1 () ,		
Jennifer Ye n tel			02-28-2	011						

IMIDACLOPRID TECHNICAL

INSECTICIDE

FOR USE IN THE MANUFACTURE OF INSECTICIDES

ACTIVE INGREDIENT:	%	B١	' W	π.
Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine		9	8.3	3%
OTHER INGREDIENTS:				
TOT	AL.	10	0 0)%

KEEP OUT OF REACH OF CHILDREN WARNING

Manufactured for:

Celsius Property B.V., Amsterdam (NL)
Neuhausen a.Rhf Branch
c/o Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Road, Suite 300
Raleigh, NC 27609

In Accordance with PR Notice 82-2 Based on Draft Labeling Dated

FEB 1-7 2011

EPA Reg. No. 83558-34

NET CONTENTS: LBS

EPA Est. No.

FIRST AID IF SWALLOWED: Call a poison control center or doctor immediately for further treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Have person sip a glass of water if able to swallow. Do not give anything by mouth to an unconscious person. IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. IF ON SKIN OR Take off contaminated clothing. **CLOTHING:** Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information. Note to Physician: No specific antidote is available. Treat symptomatically.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

May be fatal if swallowed. Do not breathe dust or vapor. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and warm water after handling and before eating, drinking or using tobacco products. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to aquatic invertebrates. Keep out of lakes, streams, or ponds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product.

Only for formulation into an insecticide for the following uses:

1. Terrestrial Food Crops: Apple, Banana and Plantain, Barley, Bushberry, Caneberry, Canola, Citrus, Coffee, Cotton, Cranberry, Cucurbit Vegetables, Fruiting Vegetables, Globe Artichoke, Grape, Greenhouse Vegetables, Head and Stem Brassica Vegetables, Herbs, Hops, Leafy Vegetables, Leafy Petiole Vegetables, Legume Vegetables, Peanut, Pecan, Pome Fruit, Pomegranate, Potato, Root Vegetables, edible seed crops for Sorghum, Soybeans, Sugarbeet, Strawberry, Stone Fruit, Tobacco, Tree Nuts, Tropical Fruit, Tuberous and Corn Vegetables, and Wheat.

Terrestrial Nonfood Crops or Residential and Commercial Outdoor: Christmas Trees, Lawns, Poplar/Cottonwood, Turfgrasses, Ornamentals.

Greenhouse Nonfood Crop or Residential and Commercial Indoor: Ornamentals

- Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- 3. Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statement on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

FOR NONREFILLABLE CONTAINER: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities by burning. If burned, stay out of smoke.

FOR REFILLABLE CONTAINER: Refillable container. Refill this container with imidacloprid only. Do not reuse this container for any other purpose. For final disposal, offer for recycling or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Do not use container in connection with food, feed, or drinking water. Completely empty container into the processing equipment. Offer for recycling if available. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Celsius Property B.V., Amsterdam (NL). All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Celsius Property B.V., Amsterdam (NL) is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Celsius Property B.V., Amsterdam (NL)'s election, the replacement of product.

Imidacloprid Technical (83558-34)(EPA App 02-17-11)

IMIDACLOPRID TECHNICAL

INSECTICIDE

FOR USE IN THE MANUFACTURE OF INSECTICIDES

ACTIVE INGREDIENT:	%	BY WT.
Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine		98.3%
OTHER INGREDIENTS:		1.7%
		100.0%

KEEP OUT OF REACH OF CHILDREN WARNING

Manufactured for:

Celsius Property B.V., Amsterdam (NL)
Neuhausen a.Rhf Branch
c/o Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Road, Suite 300
Raleigh, NC 27609

LBS

NET CONTENTS:

EPA Reg. No. 83558-34

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	FIRST AID
IF SWALLOWED:	 Call a poison control center or doctor immediately for further treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Have person sip a glass of water if able to swallow.
	Do not give anything by mouth to an unconscious person.
IF INHALED:	Move person to fresh air.
	 If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing.
	 Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	 Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	 Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.

Note to Physician: No specific antidote is available. Treat symptomatically.

PRECAUTIONARY STATEMENTS . HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

May be fatal if swallowed. Do not breathe dust or vapor. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and warm water after handling and before eating, drinking or using tobacco products. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to aquatic invertebrates. Keep out of lakes, streams, or ponds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product.

Only for formulation into an insecticide for the following uses:

1. Terrestrial Food Crops: Apple, Banana and Plantain, Barley, Bushberry, Caneberry, Canola, Citrus, Coffee, Cotton, Cranberry, Cucurbit Vegetables, Fruiting Vegetables, Globe Artichoke, Grape, Greenhouse Vegetables, Head and Stem Brassica Vegetables, Herbs, Hops, Leafy Vegetables, Leafy Petiole Vegetables, Legume Vegetables, Peanut, Pecan, Pome Fruit, Pomegranate, Potato, Root Vegetables, edible seed crops for Sorghum, Soybeans, Sugarbeet, Strawberry, Stone Fruit, Tobacco, Tree Nuts, Tropical Fruit, Tuberous and Corn Vegetables, and Wheat.

Terrestrial Nonfood Crops or Residential and Commercial Outdoor: Christmas Trees, Lawns, Poplar/Cottonwood, Turfgrasses, Ornamentals.

Greenhouse Nonfood Crop or Residential and Commercial Indoor: Ornamentals

- 2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- 3. Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statement on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

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FOR REFILLABLE CONTAINER: Refillable container. Refill this container with imidacloprid only. Do not reuse this container for any other purpose. For final disposal, offer for recycling or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Do not use container in connection with food, feed, or drinking water. Completely empty container into the processing equipment. Offer for recycling if available. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Celsius Property B.V., Amsterdam (NL). All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Celsius Property B.V., Amsterdam (NL) is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Celsius Property B.V., Amsterdam (NL)'s election, the replacement of product.

Imidacloprid Technical (83558-34)(EPA App 02-17-11)

Material to be added to an e-Jacket/Jacket

Reg. No. \$3558-34 Description: ☐ Placement within the e-Jacket/jacket: □ Default: (chronological, top = newest) ☐ File Location: (PDF page number, i.e., "before page 45") 2. ☐ Send to Data Extraction contractors this material: Newly stamped accepted label \Box Notification \Box New CSF \Box Other: Umended Cabel 3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900). Reviewer's Name: Mani Sanif

Phone: <u>703 305-5407</u> Division: Rd

Date: 02/17/20011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

FEB 1 7 2011

Ms. Jennifer Yentel Celsius Property B.V., Amsterdam (NL) c/o Mana 4515 Falls on Neuse Rd., Suite 300 Raleigh, NC 27609

Subject:

Amended Me-Too Technical Label for the Addition of Crops

Imidacloprid Technical Insecticide

EPA Reg. No. 83558-34

Your Submission date, December 15, 2010

Dear Ms. Yentel:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable. A stamped copy of the label is enclosed for your records. Submit two (2) copies of your final printed labeling before you release the product for shipment. If there are questions call Dani Daniel at 703 305-5409.

Sincerely.

Venus Eagle

Product Manager (01)

Insecticide-Rodenticide Branch Registration Division (7504P)

Enclosure:

IMIDACLOPRID TECHNICAL

INSECTICIDE

FOR USE IN THE MANUFACTURE OF INSECTICIDES

ACTIVE INGREDIENT:		BY WT.
lmidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine		98.3%
OTHER INGREDIENTS:		
7	TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN WARNING

ACCEPTED

Manufactured for:

FEB 1 7 2011 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, forcinsus Property B.V., Amsterdam (NL)

pesticide registered under:

Neuhausen a.Rhf Branch

c/o Makhteshim Agan of North America, Inc. 4515 Falls of Neuse Road, Suite 300

Raleigh, NC 27609

EPA Reg. No. 83558-34

NET CONTENTS: LBS EPA Est. No.

FIRST AID						
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 Do not induce vomiting unless told to do so by a poison control center or doctor. 						
	 Have person sip a glass of water if able to swallow. 					
	 Do not give anything by mouth to an unconscious person. 					
IF INHALED:	Move person to fresh air.					
	 If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. 					
IF ON SKIN OR CLOTHING:	Take off contaminated clothing.					
	 Rinse skin immediately with plenty of water for 15-20 minutes. 					
	 Call a poison control center or doctor for treatment advice. 					
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.					
	 Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. 					
	Call a poison control center or doctor for treatment advice.					
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LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS**, **DISCLAIMER OF WARRANTIES**, and **LIMITATIONS OF LIABILITY**.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Celsius Property B.V., Amsterdam (NL). All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Celsius Property B.V., Amsterdam (NL) is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Celsius Property B.V., Amsterdam (NL)'s election, the replacement of product.

Imidacloprid Technical (83558-34) (EPA Registered 10-21-09) (Amend to EPA 12-15-10)

Please read instructions	on reverse before comple	ling form.		Form Appr	oved. C	OMB No. 207	0-0060	Print Form	
⊕EPA	Environmental	nited States Protection agton, DC 20460	Agency		\times	Registrat Amendm Other		OPP Identifier Number	
		Application	or Pestic	de - Seci	tion I	_		t	
1. Company/Product Nur 83558-34	mber			Product Man Eagle	eger			posed Classification	
4. Company/Product (Na Imidacloprid Technic			PM# 1		-			None Restricted	
Celsius Property B.V., c/o MANA, 4515 Falls Raleigh, NC 27609	Applicant Include ZIP Co Amsterdam (NL) of Neuse Rd, Suite 300 this is a new address	-	6. Expedited Review. (n accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 264-755; 81598-5 Bayer Imdaclopid. Technical Product Name Rotam Linual clopid Technical						
			Section -	11					
Notification - Exp	response to Agency letter		×	Final printed Agency lett "Me Too" A Other - Exp	ter dated Applicati	ion.	to		
Amendment applicati	ion to add crops to proc		RIA Fee 90-da		•	······································			
1. Material This Product	Will Be Packaged In:								
Child-Resistant Peckagin Yes* X No Certification must be submitted	Yes X No	No. per	Yes Yes No Yes' Yes' Yes' Yes' Yes' Yes'	Packaging No. per		2. Type of C	ontainer Metal Plestic Glase Paper Other (S	pecify)	
3. Location of Nat Conte	nts Information	4. Size(s) Retail (ontainer		5 <u>, Loc</u>	ation of Labe	Directio	ns	
Label 6. Manner in Which Label	Container	Lithograph					al oling accompanying product		
		Lithograph Paper glue Stenciled	d	hand					
			Section -						
	lete items directly below f			e contacted,	if neces				
Name Jennifer Yentel	Tet Re	तिश्व Regulatory Specialist				Telephone No. (Include Area Code) 919-256-93 5			
	tetements i have made on It eny knowingly false or n Ibia law.		attachments t					6. Dets Application Recei⊎ed (Stamped)	
2. Signatura		3. Title Regulatory Specialist				3			
4. Typed Name		5. t	ate					Cons	

12/15/2010

Jennifer Yentel



Makhteshim Agan of North America, Inc.

December 15, 2010

Document Processing Desk (AMEND)
Office of Chemical Safety and Pollution Prevention (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Venus Eagle (PM 1), Registration Division

Phone: 703-308-8045

Re: Imidacloprid Technical, EPA Reg. No. 83558-34

Application to Amend, No PRIA Fee, 90-Day Fast Track - Adding Crops

Dear Ms. Eagle,

Celsius Property B.V., Amsterdam (NL) c/o Makhteshim Agan of North America, Inc., is submitting an application to amend its Imidacloprid Technical product label by adding additional crops. We are me-tooing Bayer CropScience's Imidacloprid Technical (EPA Reg. No. 264-755) and Rotam Ltd's Rotam Imidacloprid Technical (EPA Reg. No. 81598-5) labels. We are citing Residue Chemistry Data submitted by Bayer Corp., Bayer CropScience LP, and Interregional Research Project No. 4.

In support of this submission, the following documents are attached:

- Application for Pesticide Registration (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Five copies of draft label
- One copy of annotated label
- Copies of the labels that we are me-tooing

Should you have any questions about this application, please contact me at 919-256-9315 or e-mail at jyentel@manainc.com.

Sincerely,

Jennifer Yentel

Regulatory Specialist

Enclosures

Home Page > Executive Branch > Code of Federal Regulations > Electronic Code of Federal Regulations



e-CFR Data is current as of February 15, 2011

Title 40: Protection of Environment

PART 180—TOLERANÇES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD Subpart C—Specific Tolerances

Browse Previous | Browse Next

§ 180.472 Imidacloprid; tolerances for residues.

(a) General. Tolerances are established for residues of the insecticide imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyndinyl) methyl]- N -nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid, in or on the following commodities:

Commodity	Parts per million
Acerola	1.0
Almond, hulls	4.0
Apple	0.5
Apple, wet pomace	3.0
Artichoke, globe	2.5
Aspirated grain fractions	240
Atemoya	0.30
Avocado	1.0
Banana	0.50
Beet, sugar, molasses	0.30
Beet, sugar, roots	0.05
Beet, sugar, tops	0.50
Biriba	0.30
Blueberry	3.5
Borage, seed	0.05
Caneberry, subgroup 13-A	2.5
Canistel	1.0
Canola, seed	0.05
Cattle, fat	0.30
Cattle, meat	0.30
Cattle, meat byproducts	0.30

Cherimoya	0.30
Citrus, dried pulp	5.0
Coffee, bean, green	0.80
Cotton, gin byproducts	4.0
Cotton, meal	8.0
Cotton, undelinted seed	6.0
Crambe, seed	0.05
Cranberry	0.05
Currant	3.5
Custard apple	0.30
Egg	0.02
Elderberry	3.5
Feijoa	1.0
Flax, seed	0.05
Fruit, citrus, group 10	0.70
Fruit, pome, group 11	0,6
Fruit, stone, group 12	3.0
Goat, fat	0.30
Goat, meat	0.30
Goat, meat byproducts	0.30
Gooseberry	3.5
Grain, cereal, forage, fodder and straw, group 16, forage, except rice	7.0
Grain, cereal, forage, fodder and straw, group 16, hay, except rice	6.0
Grain, cereal, forage, fodder and straw, group 16, stover, except rice	0.30
Grain, cereal, forage, fodder and straw, group 16, straw, except rice	3.0
Grain, cereal, group 15, except rice	0.05
Grape	1.0
Grape, juice	1.5
Grape, raisin	1.5
Guava	1.0
Herbs subgroup 19A, dried herbs	48
Herbs subgroup 19-A, fresh herbs	8.0
Hog, fat	0.30
Hog, meat	0.30
Hog, meat byproducts	0.30
Hop, dried cones	6.0
Horse, fat	0.30
Horse, meat	0.30
Horse, meat byproducts	0.30

Huckleberry	3.5
Ilama	0.30
Jaboticaba	1.0
Juneberry	3.5
Kava, leaves	4.0
Kava, roots	0.40
Leaf petioles subgroup 4B	6.0
Leafy greens subgroup 4A	3.5
Lettuce, head	3.5
Lettuce, leaf	3.5
Lingonberry	3.5
Longan	3.0
Lychee	3.0
Mango	1.0
Milk	0.10
Mustard, black, seed	0.05
Mustard, field, seed	0.05
Mustard, Indian, seed	0.05
Mustard, rapeseed, seed	0.05
Mustard, seed	0.05
Nut, tree, group 14	0.05
Okra	1.0
Onion, dry bulbs, subgroup 3-07A	0.15
Onion, green, subgroup 3-07B	2.5
Papaya	1.0
Passionfruit	1.0
Peanut	0.45
Peanut, hay	35
Peanut, meal	0.75
Pecan	0.05
Persimmon	3.0
Pistachio	0.05
Pomegranate	0.90
Potato, chip	0.40
Potato, processed potato waste	0.90
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Pulasan	3.0
Rambutan	3.0
Rapeseed, seed	0.05
Raspberry, wild	2.5

Safflower, seed	0.05
Salal	3.5
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
Sheep, fat	0.30
Sheep, meat	0.30
Sheep, meat byproducts	0.30
Soursop	0.30
Soybean, forage	8.0
Soybean, hay	35
Soybean, meal	4.0
Soybean, seed	3.5
Spanish lime	3.0
Star apple	1.0
Starfruit	1.0
Strawberry	0.50
Sugar apple	0.30
Sunflower, seed	0.05
Tomato, paste	6.0
Tomato, puree	3.0
Vegetable, brassica leafy, group 5	3.5
Vegetable, cucurbit, group 9	0.5
Vegetable, fruiting, group 8	1.0
Vegetable, leaves of root and tuber, group 2	4.0
Vegetable, legume, group 6, except soybean	4.0
Vegetable, root and tuber, group 1, except sugar beet	0.40
Watercress	3.5
Watercress, upland	3.5
Wax jambu	1.0

(b) Section 18 emergency exemptions [Reserved]

(c) Tolerances with regional registrations . [Reserved]

(d) Indirect or inadvertent residues. Tolerances are established for indirect or inadvertent residues of the insecticide imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl) methyl]- N -nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid, in or on the following commodities, when present therein as a result of the application of the pesticide to growing crops listed in this section and other non-food crops as follows:

Commodity	Parts per million
Rice, grain	0.05
Vegetable, foliage of legume, group 7	2.5

0.3	Vegetable, legume, group 6
	[75 FR 22251, Apr. 28, 2010]
	Browse Previous Browse Next
	Browse Previous Browse Next

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Certification with Respect to C	Citation of Data	·				
Applicant's/Registrant's Name, Address, and Telephone Number Celsius Property BV, c/o MANA Inc., 4515 Falls of Neuse Rd, Ste 300, Raleigh, NC 27609 EPA Registration Number/File Symbol 83558-34						
Active Ingredient(s) and/or representative test compound(s) Imidacloprid		Date 02/03/201t				
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 Terrestrial non-food crop, Terrestrial food crop, greenhouse non-food crop)	Product Name Imidacloprid Technical				
NOTE: If your product is a 100% repackaging of another purchased EPA-registers submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator's		r all the same uses on your label, you do not need to				
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies se	nt offers of compensation (the Data Matrix form should				
SECTION 1: METHOD OF DATA SUPF	ORT (Check one m	ethod only)				
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	the selective method of support (or cite-all option selective method), and have included with this form a I list of data requirements (the Data Matrix form must be				
SECTION II: GENERAL	OFFER TO PAY					
[Required if using the cite-all method or when using the cite-all option under the select	tive method to satisf	y one or more data requirements]				
I hereby offer and agree to pay compensation, to other persons, with regard to	the approval of this	application, to the extent required by FIFRA.				
SECTION III: CERT	IFICATION					
I certify that this application for registration, this form for reregistration, or that application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application souguses.	addition, if the cite-a t (1) concern the pro is a type of data that	Il option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data				
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, the	If I am the original data submitter or that I have obtained				
I certify that for each study cited in support of this registration or reregistration submitter; (b) I have obtained the permission of the original data submitter to use the scompensation have expired for the study; (d) the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(d) amount and terms of compensation, if any, to be paid for the use of the study.	study in support of th I have notified in wri	is application; (c) all periods of eligibility for ting the company that submitted the study and have				
I certify that in all instances where an offer of compensation is required, cop accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will te evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	e submitted to the A	gency upon request. Should I fail to produce such				
i certify that the statements I have made on this form and all attachm knowingly false or misleading statement may be punishable by fino or impriso						
Signature	Date	Typed or Printed Name and Title				
geunge ye it et	02/03/2011	Jennifer Yentel, Regulatory Specialist				

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	DA	TA MATRIX			
Date 2/17/2011			EPA Reg No./File Symbol 83558-34		Page 1 of 15
The state of the s		Product Imidacloprid Technical			
Ingredient Imidacloprid (CAS No. 1	38261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	47344704	Celsius Property B.V. (Amsterdam NL)	OWN	
830.1600	Description of Materials Used to Produce the Product	47344704	Celsius Property B.V. (Amsterdam NL)	OWN	-
930.1620	Description of Production Process	47344704	Celsius Property B.V. (Amsterdam NL)	OWN	
930.1670	Discussion of the Formation of Impurities	47344704	Celsius Property B.V. (Amsterdam NL)	OWN	
830.1700	Preliminary Analysis	47344704	Celsius Property B.V. (Amsterdam NL)	OWN	
B30.1750	Certifled Limits	47344704	Celsius Property B.V. (Amsterdam NL)	OWN	
B30,1800	Enforcement Analytical Method	47424401	Bayer CropScience LP	PAY	
330.6302	Color .	47722,202	Cetsius Property B.V. (Amsterdam NL)	OWN	
330.6303	Physical State	47722202	Celsius Property B.V. (Amsterdam NL)	OWN	
330.6304	Odor	47722202	Celsius Property B.V. (Amsterdam NL)	OWN	
330.6313	Stability to normal and elevated temperatures, metals	47722202	Celsius Property B.V. (Amsterdam NL)	OWN	
	and metal lons				
330.6314	Oxidation/Reduction	47722206	Celsius Property B.V. (Amsterdam NL)	OWN	
330.6315	Flammability	47439801	Celsius Property B.V. (Amsterdam NL)	OWN	
B30.6316	Explodability	47439801	Celsius Property B.V. (Amsterdam NL)	OWN	
Signature	u gentel		Name and Title Jennifer Yentel, Regulatory Specialist		Date 02/17/2011

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send the form to this address.			***************************************		
		DATA MATRIX			
Date 2/17/2011			EPA Reg No./File Symbol 83558-34		Page 2 of 15
Applicant's/Registrant's Name & Address Cetsius Property B.V. (Amsterdam NL) c/o MANA, 4515 Falls of Neuse Rd., Suite 300, Rateigh, NC 27609		Product Imidacloprid Technical			
Ingredient tmidacloprid (CAS No.	138261-41-3)				
Guidetine Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability	48330201	Cetslus Property B.V. (Amsterdam NL)	OWN	
830.6319	Miscibitity	47439801	Celsius Property B.V. (Amsterdam NL)	OWN	
830.6320	Corrosion Characteristics	48330201	Celsius Property B.V. (Amsterdam NL)	OWN	
830.7000	рН	47722202	Celsius Property B.V. (Amsterdam NL)	OWN	
830.7050	UV/Visible Light Absorption	47439801	Cetsius Property B.V. (Amsterdam NL)	OWN	
830.7200	Melting point / Melting range	47439801	Celsius Property B.V. (Amsterdam NL)	OWN	
830.7300	Density / relative density / bulk density	47722202	Celsius Properly B.V. (Amsterdam NL)	OWN	
830.7550	Partition coefficient .	47439801	Celsius Property B.V. (Amsterdam NL)	OWN	
830.7840	Water Solubility	47439801	Cetsius Property B.V. (Amsterdam NL)	OWN	
830.7950	Vapor Pressure	47439801	Celsius Property B.V. (Amsterdam NL)	OWN	
MATERIAL DE LA CONTRACTION DEL CONTRACTION DE LA CONTRACTION DEL CONTRACTION DE LA C					

Signature			Name and Title Jennifer Yentel, Regulatory Specialist		Date 02/17/2011
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		DATA MATRIX			
Date 2/17/2011			EPA Reg No./File Symbol 83558-34		Page 3 of 15
Applicant's/Registrant's Name & Address Celsius Property B.V. (Amsterdam NL) c/o MANA, 4515 Falls of Neuse Rd., Suite 300, Raleigh, NC 27609		Product Imidacloprid Technical			
ingredient Imidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All Other Data Requirements		Syngenta Crop Protection, Inc.	PAY	
			PO Box 18300		
			Greensboro, NC 27419		
·			Nufarm Americas Inc.	PAY	
			150 Harvester Drive, Sulte 200		
			Burr Ridge, IL 60527		
			Bayer CropScience LP	PAY	
			PO Box 12014	-	
			2 T.W. Alexander Drive		
			Research Triangle Park, NC 27709		
			FMC Corp Agricultural Products Group	PAY	
			1735 Market Street, Room 1978		
			Philadelphia, PA 19103		
	-				
Signature			Name and Title		Date
CXI IA AL	if bentel		Jennifer Yentel, Regulatory Specialist		02/17/2011

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		DATA MATRIX			
Applicant's/Registrant's Name & Address		EPA Reg No./File Symbol 83558-34		Page 4 of 15	
		Product Imidacloprid Technical			
ngredient Imidacloprid (CAS No	. 138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Stat⊔s	Note
	All other data requirements, continued		Chemtura Corporation	PAY	
			199 Benson Road (2-5)		
			Middlebury, CT 06749		
			Bayer Environmental Science	PAY	
			PO Box 12014		
			2 T.W. Alexander Drive		
			Research Triangle Park, NC 27709		
			The Scotts Company	PAY	
			14111 Scottslawn Road		
			Marysville, OH 43041		
			Cleary Chemicals, LLC	PAY	
· · · · · · · · · · · · · · · · · · ·			178 Ridge Road, Suite A		
			Dayton, NJ 08810		
Signature	mile water		Name and Title Jennifer Yentel, Regulatory Specialist		Date 02/17/2011

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		DATA MATRIX			
		DATA MATRIA			I
Date 2/17/2011			EPA Reg No./File Symbol 83558-34		Page 5 of 15
Applicant's/Registrant's Name & Address Celsius Property B.V. (Amsterdam NL) c/o MANA, 4515 Falls of Neuse Rd., Suite 300, Raleigh, NC 27609		Product Imldacloprid Technical			
Ingredient Imidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		PBI Gordon Corp	PAY	
			PO Box 014090		
			1217 West 12th Street		
			Kansas City, MO 64101		
			Bayer Corp	PAY	
			PO Box 4913		
			8400 Hawthorn Road		
			Kansas City, MO 64120		
			Helena Chemical Co	PAY	
			7684 Moore Road		
			Memphis, TN 38120		
			Gustafson LLC	PAY	
			PO Box 660065		
			Dallas, TX 75266		
. , , , , , , , , , , , , , , , , , , ,					
Signature Name and Title		Date			
O**	ye byntel		Jennifer Yentel, Regulatory Specialist		02/17/2011

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		DATA MATRIX			
Date 2/17/2011			EPA Reg No./File Symbol 83558-34		Page 6 of 15
		Product Imidacloprid Technical			
Ingredient Imidacloprid (CAS No	. 138261-41-3)				
Guideline Reference Number	Guidetine Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		J.J. Mauget Co.	PAY	
		ļ	12733 Director's Loop		
			Woodbridge, VA 22192		
			The Andersons Lawn Fertilizer Division	PAY	
			PO Box 119		
			Maumee, OH 43537		
			Chemical Specialties Inc.	PAY	
-			PO Box 1330		
			Harrisburg, NC 28075		
			Bayer Healthcare LLC	PAY	
			PO Box 390		
			Shawnee Mission, KS 66201		
			Mitsui Chemicals, Inc.	PAY	
			PO Box 5126		
			Valdosta, GA 31603		
Signature	nule knitel		Name and Title Jennifer Yentel, Regulatory Specialist		Date 02/17/2011

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		DATA MATRIX			
ate 2/17/2011			EPA Reg No./File Symbol 83558-34		Page 7 of 15
		Product Imidacloprid Technical			
ngredient Imidacloprid (CAS No. 1	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
	All other data requirements, continued		Loveland Products Inc.	PAY	
			PO Box 1286		
			Greeley, CO 80632		
			Nufarm Limited	PAY	
			PO Box 13439		
			Research Triangle Park, NC 27709		
			Lanxess Corporation	PAY	
			111 RIDC Park West Drive		
			Pittsburgh, PA 15275		
			Albaugh, inc.	PAY	
			1525 NE 36th Street		
			Ankeny, tA 50021		
· · · · · · · · · · · · · · · · · · ·			Aeroxon inc.	PAY	
			2125 Center Avenue, Suite 507		
			Fort Lee, NJ 07024		
ignature	ennyly Wentel	I	Name and Title Jennifer Yentel, Regulatory Specialist		Date 02/17/2011

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		DATA MATRIX			
Date 2/17/2011	***************************************		EPA Reg No./File Symbol 83558-34		Page 8 of 15
Applicant's/Registrant's Name & Address Celsius Property B.V. (Amsterdam NL) c/o MANA, 4515 Falls of Neuse Rd., Suite 300, Raleigh, NC 27609		Product Imidacloprid Technical			
Ingredient Imidacloprid (CAS No.	. 138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Control Sotutions, Inc.	PAY	
			5903 Genoa-Red Bluff		
			Pasadena, TX 77507		
			Nufarm Americas Inc.	PAY	
			150 Harvester Drive, Suite 200		
			Burr Ridge, IL 60527		
			Spray Drift Task Force	MEM	
,			1900 K Street, NW	,	
			Washington, DC 20006		
			Cheminova, Inc.	PAY	
			1600 Wilson Blvd, Suite 700		
			Arlington, VA 22209		
			Mycogen Seeds	PAY	
			9330 Zionsville Road		
			Indianapolis, IN 46268		
Signature			Name and Title		Date
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	serne bentel		Jennifer Yentel, Regulatory Specialist		02/17/2011

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		DATA MATRIX			
Date 2/17/2011	· · · · · · · · · · · · · · · · · · ·		EPA Reg No./File Symbol 83558-34		Page 9 of 15
		Product ImIdacloprid Technical			
Ingredient Imidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Arbor Systems, LLC	PAY	
			8203 West 20th St., Suite A		
			Greeley, CO 80634		
			Pet Logic, LLC	PAY	
			PO Box 540224		
			Omaha, NE 68130		
			Repar Corp	PAY	
			1050 Connecticut Ave., NW, Suite 1000		
			Washington, DC 20036		
			United Phosphorus, Inc.	PAY	
			630 Freedom Business Center, Suite 402		
			King of Prussia, PA 19406		
			Sulphur Mills, Ltd	PAY	
			12208 Quinque Lane		
			Clifton, VA 20124		
Signature		-	Name and Title		Date
	eany yestal		Jennifer Yentel, Regulatory Specialist		02/17/2011

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Applicant's/Registrant's Name & Address Celsius Property B.V. (Amsterdam NL) c/o MANA, 4515 Falls of Neuse Rd., Suite 300, Rateigh, NC 27609		EPA Reg No./File Symbol 83558-34 Page O of 15 Product Imidacloprid Technical			
Ingredient Imidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Nate
	All other data requirements, continued		Nufarm, Inc.	PAY	
			150 Harvester Drive, Suite 200		
			Burr Ridge, IL 60527		
			ISK Biosciences Corporation	PAY	
			7470 Auburn Road, Suite A		
			Concord, OH 44077		
			Outdoor Residential Exposure Task Force	МЕМ	
-			1350 I Street, NW		
			Washington, DC 20005		
			Agricultural Reentry Task Force	мем	
			1350 I Street, NW		
			Washington, DC 20005		
			Bayer Advanced	PAY	
			PO Box 12014; 2 T.W. Alexander Drive		
			Research Triangle Park, NC 27709		
Signature			Name and Title		Date
Je ringe We at I			Jennifer Yentel, Regulatory Specialist		02/17/2011

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		DATA MATRIX			
Date 2/17/2011 Applicant's/Registrant's Name & Address Celsius Property B.V. (Amsterdam NL) c/o MANA, 4515 Falls of Neuse Rd., Suite 300, Raleigh, NC 27609		EPA Reg No./File Symbol 83558/34		Page 1 of 15	
		Product Imidacloprid Technical			
Ingredient tmidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Agrisel USA, Inc.	PAY	
			400 East Jane Street		
			Valdosta, GA 31601		
			Scimetrics, Ltd. Corporation	PAY	
			PO Box 1045; 9974 NE Frontage Road		
			Wellington, CO 80549		
			Zelam Ltd.	PAY	
			17220 Westview Road		
			Lake Oswego, OR 97034	:	
			Rockwell Laboratories, Ltd,	PAY	
			1512 Taney Street		
,			North Kansas City, MO 64116		
			Sapstain Industry Group (SIG)	PAY	
			1125 Trenton-Harbourton Road		
			Titusville, NJ 09560		
Signature			Name and Title		Date
Senne Gentel			Jennifer Yentet, Regulatory Specialist		02/17/2011

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		Product Imidacloprid Technical			
ngredlent Imidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Słudy Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Univar USA Inc	PAY	
			115 Obtuse Hill Road		
			Brookfield, CT 06804		
			Innovative Pest Control Products	PAY	
			PO Box 880216		
			Boca Raton, FL 33488		
			FIFRA Endangered Species Task Force LLC	PAY	
	·		1350 i Street, NW		
			Washington, DC 20005		
			Arborjet	PAY	
			12510 Prosperity Drive, Suite 160		
100000000000000000000000000000000000000			Silver Spring, MD 20904		
			Residential Exposure Joint Venture	PAY	
			900 17th Street, NW, Suite 300		
			Washington, DC 20006		
Signature Name and Title			Date		
geante goutel			Jennifer Yentel, Regulatory Specialist		02/17/2011

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		Product Imidacloprid Technical			
gredient Imidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Agricultural Handlers Exposure Task Force	MEM	
			PO Box 509; 1720 Prospect Drive		
			Macon, MO 63552		
			Arch Treatment Technologies, Inc.	PAY	
			5660 New Northside Drive, Suite 1100		
			Atlanta, GA 30328		<u> </u>
			Gro-Pro LLC	PAY	
-			4110 136th Street, NW		
			Gig Harbor, WA 98332		
			Rotam Limited	PAY	
			4032 Crockers Lake Blvd, Suite 818		
			Sarasota, FL 43238		
**************************************			Etigra LLC	PAY	
***************************************			4110 136th Street, NW		
***************************************			Gig Harbor, WA 98332		
Signature	Sund Gentel		Name and Title Jennifer Yentel, Regutatory Specialist		Date 02/17/2011

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		NC 27609	Product Imidacloprid Technical		
Ingredient Imidacloprid (CAS No.	138261-41-3)				
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
	All other data requirements, continued		Sharda Worldwide Exports PVT LTD	PAY	
			7460 Lancaster Pike, Suite 9		
			Hockessin, DE 19707		
			Ensystex III, Inc.	PAY	
			4110 136th Street, NW		
			Gig Harbor, WA 98332		
			Rotam Agrochemical Company Limited	PAY	
			4032 Crockers Lake Blvd, Suite 818		-
			Sarasota, FL 43238		
			J. Oliver Products, LLC	PAY	
			115 Obtuse Hill Road		
			Brookfield, CT 06804		
			Sharda USA LLC	PAY	
			7460 Lancaster Pike, Suite 9		
			Hockessin, DE 19707		
Signature			Name and Title		Date
Jennifer Yernel, Regulatory Specialist			02/17/2011		

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Date 2/17/2011			EPA Reg No./File Symbol 83558-34 Page 15 of Product Imidacloprid Technical		Page 15	
Applicant's/Registrant's Name & Address Celsius Property BV (Amsterdam NL) c/o MANA, 4515 Falls of Neuse Rd., Suite 300, Raleigh, NC 27609						
ngredient tmldacloprid (CAS No.	. 138261-41-3)					
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
	All other data requirements, continued		Amtide, LLC	PAY		
			21 Hubble			
			Irvine, CA 92618			
			Ensystex tV, Inc.	PAY		
			4110 136th Street, NW			
			Gig Harbor, WA 98332			
			Dalian Chemphy Chemicals Co., Ltd.	PAY		
		-	1150 18th Street, NW, Suite 1000			
			Washington, DC 20036			
			Generic Endangered Species Task Force	MEM		
			4110 136th Street, Northwest			
			Gig Harbor, WA 98332			
			Abamax Chemical LLC	PAY		
			PO Box 640; 7460 Lancaster Pike, Suite 9			
			Hockessin, DE 19707			
Signature	Al MALL AR MALL		Name and Title Jennifer Yentel, Regulatory Specialist		Date 02/17/2011	

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November 16, 2009

Document Processing Desk (FINLABEL) Office of Pesticide Programs (7504P) US EPA One Potomac Yard 2777 Crystal Drive, Room S-4900 Arlington, VA 22202

Attn:

Venus Eagle, Product Manager 01 Insecticide-Rodenticide Branch Registration Division (7505P)

Subject:

Response to Agency Letter and Certificate of Registration Dated October 21, 2009

Imidacloprid Technical (EPA Reg. No. 83558-34)

Dear Ms. Eagle;

Makhteshim Agan of North America Inc., on behalf of Celsius Property, BV is submitting two (2) copies of final printed labeling per the subject letter.

If you have any questions or concerns regarding this information, please contact me at (919) 256-9323, or lpruett@manainc.com.

Sincerely,

P. Leanne Pruett

Regulatory Product Manager

Makhteshim Agan of North America, Inc.

Please read instructions on rev	erse before care pleting form.	Form Approved.	B No. 2070-0060	. Approval expires 11-30-93
EPA	United States Environmental Protection Washington, DC 20460	□ Registr Agency □ Amend • Other		OPP Identifier Number
	Application	for Pesticide -Section I		
1. Company/Product Number 83558-34		EPA Product Manager Venus Eagle	3. Proposed Classification	
Company/Product (Name) Imidacloprid Technical		PM# 01		
5. Name and Address of Applications Celsius Property BV (I Makhteshim-Agan of I 4515 Falls of Neuse F Raleigh, NC 27609 □ Check if this is a new add	Neuhasen a Rhf Branch) North America, Inc. dd., Suite 300,	Expedited Review. In accordance product is similar or identical in a EPA Reg. No. Product Name		
	S	ection I I		
□ Notification - Explain below	to Agency letter dated	♣ Final printed labels in respon ☐ "Me Too" Application ☐ Other - explain below section II).	nse to Agency letto	er dated <u>Oct 21, 2009</u>
	Se	ection		
1. Material This Product Will E	e Packaged In:			
Child-Resistant Packaging Yes* No *Certification must be submitted.	Unit Packaging ☐ Yes ☐ No ☐ No If "Yes," Unit Package Wt. Container	Water Soluble Packaging ☐ Yes ☐ No If "Yes," No. Per Package Wt. Container	2. Type of Con Metal Plastic Glass Paper Other (Sp	
3. Location of Net Contents Information		Size(s) of Retail Container	5. Location of Label Directions On Label On Labeling accompanying product	
6. Manner In Which Label Is Aff		☐ Other ()		ing decompanying product
	Se	ection I V		
Contact Point (Complete item	s directly below for identification of indivi	idual to be contacted, if necessary	, to process this a	pplication.)
Name Leanne Pruett		Title Regulatory Product Manager	Telephone No. (919) 256-9	(Include Area (Code) 323
	Certification e made on this form and all attachments y false or misleading statement may be p			Date Application Recrived (Stamped)
2. Signature	2/-	Title Regulatory Product Mana	ıger	
4. Typed Name P. Leanne Pruett		5. Date 11-16-09	Date	

IMIDACLOPRID TECHNICAL

INSECTICIDE

FOR USE IN THE MANUFACTURE OF INSECTICIDES

ACTIVE INGREDIENT:	% BY WT.
Imidacloprid, 1-f(6-Chloro-3-pyridinyl)methyll-N-nitro-2-imidazolidinimine.	
Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine. OTHER INGREDIENTS: În	NOT REVIEWED
ኒያ ''	Accordance with PK HOHCE 82 60 0%
Sa S	ised on Draft Labeling Jated
	UUI & I ZUUS

KEEP OUT OF REACH OF CHILDREN **WARNING**

Manufactured for:

Celsius Property B.V., Amsterdam (NL) Neuhausen a.Rhf Branch c/o Makhteshim Agan of North America, Inc. 4515 Falls of Neuse Road, Suite 300 Raleigh, NC 27609

LBS

NET CONTENTS:

EPA Reg. No. 83558-34

EPA Est. No.

	FIRST AID	
IF SWALLOWED:	 Call a poison control center or doctor immediately for further treatment advice. 	
	 Do not induce vomiting unless told to do so by a poison control center or doctor. 	
	 Have person sip a glass of water if able to swallow. 	
	 Do not give anything by mouth to an unconscious person. 	
IF INHALED:	Move person to fresh air.	
	 If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. 	
	Call a poison control center or doctor for further treatment advice.	
IF ON SKIN OR CLOTHING:	Take off contaminated clothing.	
	 Rinse skin immediately with plenty of water for 15-20 minutes. 	
	 Call a poison control center or doctor for treatment advice. 	
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.	
	 Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. 	
	Call a poison control center or doctor for treatment advice.	
	ontainer or label with you when calling a poison control center or doctor or going for also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

Note to Physician: No specific antidote is available. Treat symptomatically.

May be fatal if swallowed. Do not breathe dust or vapor. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and warm water after handling and before eating, drinking or using tobacco products. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to aquatic invertebrates. Keep out of lakes, streams, or ponds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product.

Only for formulation into an insecticide for the following uses:

1. Terrestrial Food Crops: Apple, Barley, Bushberry, Canola, Citrus, Cotton, Cranberry, Cucurbit Vegetables, Grape, Greenhouse Vegetables, Fruiting Vegetables, Head and Stem Brassica Vegetables, Leafy Vegetables, Leafy Petiole Vegetables, Legume Vegetables, Hop, Pecan, Pome Fruit, Potato, Root Vegetables, edible seed crops for Sorghum, Sugarbeet, Strawberry, Stone Fruit, Tropical Fruit, Tuberous and Corn Vegetables, and Wheat.

Terrestrial Nonfood Crops or Residential and Commercial Outdoor: Lawns, turfgrasses, ornamentals.

Greenhouse Nonfood Crop or Residential and Commercial Indoor: Ornamentals

- 2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- 3. Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statement on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

FOR NONREFILLABLE CONTAINER: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities by burning. If burned, stay out of smoke.

FOR REFILLABLE CONTAINER: Refillable container. Refill this container with imidacloprid only. Do not reuse this container for any other purpose.

Do not use container in connection with food, feed, or drinking water. Completely empty container into the processing equipment. Offer for recycling if available. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

FOR 24-HOUR EMERGENCY ASSISTANCE (SPILL, LEAK OR FIRE), CALL INFOTRAC AT 1-800-535-5053.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS**, **DISCLAIMER OF WARRANTIES**, and **LIMITATIONS OF LIABILITY**.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Celsius Property B.V., Amsterdam (NL). All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Celsius Property B.V., Amsterdam (NL) is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Celsius Property B.V., Amsterdam (NL)'s election, the replacement of product.

Imidacloprid Technical (83558-34) EPA Registered 10-21-09



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

EPA	Reg.	Num	ber:
-----	------	-----	------

Date of Issuance:

83558-34

OCT 21 0000

NOTICE OF PESTICIDE:

X Registration Reregistration

(under FIFRA, as amended)

Term of Issuance:
Conditional

Name of Pesticide Product:

Imidacloprid Technical

Name and Address of Registrant (include ZIP Code):

Celsius Property, BV

c/o Makhteshim-Agan of North America, Inc.

4515 Falls of Neuse Rd.; Suite 300

Raleigh, NC 27609

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

- Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
- Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 83558-34".
- Submit one copy of the revised final printed label for the record before you release the product for shipment.

Signature of Approving Official:

Date:

OCT 2 1 3009

Venus Eagle, Product Manager (01)

Insecticide-Rodenticide Branch, Registration Division (7505P)

Page 2 EPA Reg. No. 83558-34

4. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this notice, please contact Kable Bo Davis at (703) 306-0415.

Venus Eagle Product Manager (01) Insecticide-Rodenticide Branch Registration Division (7505P)

Enclosure- Stamped Labeling

IMIDACLOPRID TECHNICAL

INSECTICIDE

FOR USE IN THE MANUFACTURE OF INSECTICIDES

ACTIVE INGREDIENT:	% BY WT
Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine	98.3%
OTHER INGREDIENTS:	ACCER 25 1.7%
Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine OTHER INGREDIENTS:	with CONTOTAL 100.0%
	In EPA Letter Dated:
KEEP OUT OF REACH OF CHILDRE	N and a short

KEEP OUT OF REACH OF CHILDREN WARNING

Manufactured for:

Celsius Property B.V., Amsterdam (NL)
Neuhausen a.Rhf Branch
c/o Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Road, Suite 300
Raleigh, NC 27609

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EPA Reg. No. 83558--xxx

NET CONTENTS: LBS

	FIRST AID
IF SWALLOWED:	 Call a poison control center or doctor immediately for further treatment advice.
	 Do not induce vomiting unless told to do so by a poison control center or doctor.
	 Have person sip a glass of water if able to swallow.
	 Do not give anything by mouth to an unconscious person.
IF INHALED:	Move person to fresh air.
	 If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
	 Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing.
	 Rinse skin immediately with plenty of water for 15-20 minutes.
	 Call a poison control center or doctor for treatment advice.
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	 Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	Call a poison control center or doctor for treatment advice.
	ontainer or label with you when calling a poison control center or doctor or going for
	also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.
Note to Physician: I	No specific antidote is available. Treat symptomatically.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

May be fatal if swallowed. Do not breathe dust or vapor. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and warm water after handling and before eating, drinking or using tobacco products. Remove contaminated clothing and wash before reuse.

Page 1 of 3

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to aquatic invertebrates. Keep out of lakes, streams, or ponds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product.

Only for formulation into an insecticide for the following uses:

1. Terrestrial Food Crops: Apple, Barley, Bushberry, Canola, Citrus, Cotton, Cranberry, Cucurbit Vegetables, Grape, Greenhouse Vegetables, Fruiting Vegetables, Head and Stem Brassica Vegetables, Leafy Vegetables, Leafy Petiole Vegetables, Legume Vegetables, Hop, Pecan, Pome Fruit, Potato, Root Vegetables, edible seed crops for Sorghum, Sugarbeet, Strawberry, Stone Fruit, Tropical Fruit, Tuberous and Corn Vegetables, and Wheat.

Terrestrial Nonfood Crops or Residential and Commercial Outdoor: Lawns, turfgrasses, ornamentals.

Greenhouse Nonfood Crop or Residential and Commercial Indoor: Ornamentals

- 2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- 3. Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statement on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

FOR NONREFILLABLE CONTAINER: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities by burning. If burned, stay out of smoke.

FOR REFILLABLE CONTAINER: Refillable container. Refill this container with imidacloprid only. Do not reuse this container for any other purpose.

Do not use container in connection with food, feed, or drinking water. Completely empty container into the processing equipment. Offer for recycling if available. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

FOR 24-HOUR EMERGENCY ASSISTANCE (SPILL, LEAK OR FIRE), CALL INFOTRAC AT 1-800-535-5053.

Page 2 of 3

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Celsius Property B.V., Amsterdam (NL). All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Celsius Property B.V., Amsterdam (NL) is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Celsius Property B.V., Amsterdam (NL) disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Celsius Property B.V., Amsterdam (NL)'s election, the replacement of product.

Imidacloprid Technical (83558-xx)(to EPA 04-02-09; update 10-21-09)

Imidacloprid Tech label Leanne Pruett to: Kable Davis

10/21/2009 11:44 AM

Hi, Bo -

Here's the updated Imidacloprid tech label for you.

I made the two required changes (substituted 'OTHER' for 'INERT'; added disposal directions to nonrefillable container section of label), but I didn't add the company phone number. To date, we have chosen to not do that with our MANA / MAI company labels.

If you have any questions or need any other revisions, please let me know.

Best Regards,

P. Leanne Pruett

Regulatory Product Manager Makhteshim Agan of North America, Inc.

Tel: (919) 256-9323 Fax: (919) 256-9308



lpruett@manainc.com 083558-000xx,20090402b,IMD Tech Lbl Initial Subm PLP Update.PDF.pdf

DP BARCODE; D370706; FILE SYMBOL No.: 83558-GU (a); PRODUC I: Imidacloprid Technical

Manufacturing process information may be entitled to confidential treatment

Date: October 19, 2009

SUBJECT:

Product Chemistry Review of Imidaclopind Technical TGAI/MUP

FROM:

Shyam B. Mathur, PhD

Product Chemistry Team Leader Technical Review Branch/RD (7505C)

TO:

Kable Davis / Venus Eagle, RM 01

Insecticide-Rodenticide Branch / RD (7505C)

DP BARCODE: D370706 DECISION No.: 408528 File Symbol No.: 83558-GU(a)

PRODUCT: Imidacloprid Technical TGAI/MUP

PCC: 129099

REGISTRANT: Celsius Property BV, c/o Makhteshim Agan of North America (MANA), Inc.,

Raleigh NC, USA USE: Insecticide FOOD USE: Yes

INTRODUCTION:

The product chemistry data for the proposed Imidacloprid technical were reviewed previously by TRB (see the product chemistry reviews under DP35648 and DP364944). All the supporting product chemistry data and the proposed revised basic CSF (dated 04-01-09) were found to be acceptable. In the product chemistry review dated June 2, 2009 (DP364944), TRB concluded that the proposed product is considered to be substantially similar to the registered product with Reg. No. 264-755, provided the HED determines that the impurities present in the proposed product are not of tox concern. Therefore, TRB recommended that the impurities in question must be evaluated by HED for the toxicology characteristics. The results of HED evaluation were transmitted to the Insecticide Branch, which in turn were forwarded to TRB to re-evaluate the substantially similarity of the proposed product to the registered product based on the HED conclusions.

SUMMARY OF FINDINGS:

1. The new Confidential Statement of Formula for basic formulation (dated 04-01-09) for imidacloprid technical was found to be acceptable as per previous TRB product chemistry review. The average purity of the technical/MUP is 98.3%, as determined by the five batch analysis. The proposed certified limits for the AI are based on the standard certified limits as set forth in 40CFR§158.175(b)(2). The proposed limits for impurities $\geq 0.1\%$ are based on the preliminary analysis and expected to occur in normal commercial production. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.350 respectively.

Regarding the preser	nce of the impuriti	ies present in the p <u>ro</u>	posed imidacloprid technical, the
registrant has provided	statement (on the propose	ed CSF) that these	impurities are not of tox concern.
The Insecticide Branch	referred the data package	to the HED for the d	etermination of the toxicology
characteristics of the	mpurities present i	n the proposed produ	ict.

bp barcode: D370706; FILE SYMBOL No.: 83558-GU (a); PRODUCT: Imidacloprid Technical

*Manufacturing process information may be entitled to

confidential treatment*

CONCLUSIONS

TRB has evaluated the results of the HED determination and has concluded that:

The proposed product with File Symbol No. 83558-GU is substantially similar to the registered product with Reg. No. 264-755 from the product chemistry point of view. This conclusion is based on the HED evaluation of the toxicology characteristics of the impurities. The HED's conclusions are given below.

Based on a review of the toxicity data for the parent compound, and a structure activity relationship analysis (SAR) of the parent and the impurities, HED does not believe that the new TGAI would have a different toxicity profile than the currently-registered TGAI. Considering the levels of the impurities that would be present, HED has no further concerns. A detailed discussion of the toxicity and analysis may be found in the Confidential Appendix.

DP BARCODE: D370706; FILE SYMBOL No.: 83558-GU (a); PRODUCT: Imidacloprid Technical

CONFIDENTIAL APPENDIX

Manufacturing process information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date:

October 8, 2009

Subject:

EPA Reg. No. 83558-GU. Impurities Discussion for New Formulation.

PC Code: 129099	DP Barcode: D365777
Decision No.: 408528	Registration No.: 83558-GU
Petition No. ; NA	Regulatory Action: New Registration
Risk Assessment Type: NA	Case No.: 2675
TXR No.: NA	CAS No.: 138261-41-3
MRID No.: NA	40 CFR: 180.472

From:

Ray Kent, Ph.D., Chemist

Christine Olinger, Chemist

Health Effects Division (7509P)

To:

Kable Davis/Venus Eagle, Chief

Insecticide Branch

Registration Division (7505P)

I. Action Requested

Celsius Property BV has proposed registration of a new formulation for a technical grade (TGAI) product of imidicloprid that has a different impurity profile from the currently registered TGAI. The Registration Division (RD) has requested HED comment on impurities and their potential effects on the toxicity of the TGAI.

11. HED Conclusions

Based on a review of the toxicity data for the parent compound, and a structure activity relationship analysis (SAR) of the parent and the impurities, HED does not believe that the new TOAI would have a different toxicity profile than the currently-registered TGAL. Considering the levels of the impurities that would be present, HED has no further concerns. A detailed discussion of the toxicity and analysis may be found in the Confidential Appendix to this memorandum.

Attachments: Confidential Appendix

Page 1 of 1

DP BARCODE: D370706; FILE SYMBOL No.: 83558-GU (a); PRODUCT: Imidacloprid Technical

Pages 52-54 Manufacturing process information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date:

October 8, 2009

Subject:

EPA Reg. No. 83558-GU. Impurities Discussion for New Formulation.

PC Code: 129099	DP Barcode: D365777
Decision No.: 408528	Registration No.: 83558-GU
Petition No.: NA	Regulatory Action: New Registration
Risk Assessment Type: NA	Case No.: 2675
TXR No.: NA	CAS No.: 138261-41-3
MRID No.: NA	40 CFR: 180.472

From:

Ray Kent, Ph.D., Chemist

Christine Olinger, Chemist

09/67 111/16-Health Effects Division (7509P)

To:

Kable Davis/Venus Eagle, Chief

Insecticide Branch

Registration Division (7505P)

I. **Action Requested**

Celsius Property BV has proposed registration of a new formulation for a technical grade (TGAI) product of imidicloprid that has a different impurity profile from the currently registered TGAI. The Registration Division (RD) has requested HED comment on impurities and their potential effects on the toxicity of the TGAI.

II. **HED Conclusions**

Based on a review of the toxicity data for the parent compound, and a structure activity relationship analysis (SAR) of the parent and the impurities, HED does not believe that the new TGAI would have a different toxicity profile than the currently-registered TGAI. Considering the levels of the impurities that would be present, HED has no further concerns. A detailed discussion of the toxicity and analysis may be found in the Confidential Appendix to this memorandum.

Attachments:

Confidential Appendix

Confidential Appendix to D365777

Pages 56-58 Manufacturing process information may be entitled to confidential treatment

DP BARCODE: D364944; FILE SYMBOL No.: 83558-GU; PRODUCT: Imidacloprid Technical

The State of the S

06/02/09

Date: June 2, 2009

SUBJECT:

Product Chemistry Review of Imidacloprid Technical TGAI/MUP

FROM:

Shyam B. Mathur, PhD

Product Chemistry Team Leader

Technical Review Branch/RD (7505C)

TO:

Kable Davis / Venus Eagle, RM 01

Insecticide-Rodenticide Branch / RD (7505C)

DP BARCODE: D364944 DECISION No.: 408528 File Symbol No.: 83558-GU

PRODUCT: Imidacloprid Technical TGAI/MUP

PCC: 129099

REGISTRANT: Celsius Property BV, c/o Makhteshim Agan of North America (MANA), inc.,

Raleigh NC, USA USE: Insecticide FOOD USE: Yes

INTRODUCTION:

The Makhteshim Agan of North America (MANA), Inc., as an agent for Celsius Property BV has submitted a registration application for the new product containing a currently registered active ingredient imidacloprid technical. The Agency's record indicate that the product chemistry data for the technical imidacloprid previously submitted with MRID Nos. 47344704, 47357901, 47357902 and 47344704, the revised CSF for basic formulation (dated 06-12-08) were reviewed earlier (see Product chemistry review dated June 16, 2008 with DP350648). The substantial similarity application with Reg. No. 264-755 was denied due significant difference in the physical chemical properties (pH & density) and the impurity profiles of the two products. This application was withdrawn on August 26, 2008. For the new application for registration, the registrant will be using the same sources of supply (

and will be citing the preliminary analyses that were submitted with earlier application. In order to address the objection issues raised in the previous application, the registrant has done extensive work on pH, density and impurities in question. The registrant has provided additional product chemistry data with MRID Nos. 477222-02 through 477222-06 and a new proposed basic CSF (dated 04-01-09). In the new "me-too" application, the registrant has claimed similarity with three registered products: Bayer Imidacloprid Technical Insecticide (Reg. No. 264-755), Rotam Imidacloprid Technical (Reg. No. 81598-5) and Albaugh Imidacloprid technical (Reg. No. 42750-104).

TRB has been asked to evaluate the additional product chemistry data submitted and determine the similarity with the registered products.

DP BARCODE: D364944; FILE 5 rMBOL No.: 83558-GU; PRODUCT: Imidacloprid Technical

SUMMARY OF FINDINGS:

- 1. The registrant has submitted a new Confidential Statement of Formula for basic formulation (dated 04-01-09) for imidacloprid technical. The average purity of the technical/MUP is 98.3%, as determined by the five batch analysis. The proposed certified limits for the AI are based on the standard certified limits as set forth in 40CFR§158.175(b)(2). The proposed limits for impurities ≥ 0.1% are based on the preliminary analysis and expected to occur in normal commercial production. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.350 respectively.
- 2. Regarding the presence of the impurities present in the proposed imidacloprid technical, the registrant has provided statement (on the proposed CSF) that these impurities are not of tox concern. The Agency already has information on of the impurity commonly known as the metabolite WAK3839 and has been found to be of no tox concern at the levels present in the proposed imidacloprid technical. The information on WAK3839 was included in the previous review.
- 3. The product chemistry data submitted corresponding to guideline reference 830.6313 (stability at room & elevated temperatures and to the metal and metal ions) satisfy the data requirements of 40CFR §158.310(e). The test substance was stored at room temperature and 54°C untreated and in contact with Fe & Al powder and the corresponding acetates. In all the cases the test substance did not show any degradation or side reactions. The reactions were monitored by HPLC-UV (252 nm) with internal standard technique [MRID No. 477222-02].
- 4. The product chemistry data submitted corresponding to guideline reference 830.6314 (oxidation/reduction) satisfy the data requirements of 40CFR§158.310(e). The test substance was found to be compatible with water, 10% monoammonium phosphate, Fe powder, 10% potassium permanganate and kerosene [MRID No. 477222-06].
- 5. The product chemistry data submitted corresponding to guideline 830.7000 (pH) for two producers satisfy the data requirements of 40CFR§158.310(e). The average value of pH (1% aqueous suspension) on the 5 batches of imidacloprid technical produced in two determined to be 6.86. The average pH (1% aqueous suspension) for 5 batches of imidacloprid technical produced in two determined to be 5.88 [MRID Nos. 477222-03] and 477222-04
- 6. Due to the differences in the pH values of samples determined earlier by Product Safely Laboratory (PSL; pH = 4.91) and in the subsequent PTRL Europe Study (pH = 6.5), the registrant decided to hire a consultant to conduct an audit of the laboratory and the study in question (MRID No. 47344701). Based on the audit, there were no significant findings at PSL or in the conduct of the study. The registrant also investigated the pH values of other imidacloprid technical registrants and found the variations from maximum value of 7.42 to minimum value of 4.60. In conclusion, in light of the new data generated by the registrant and the pH ranges of currently registered imidacloprid products, the registrant (Celsius) has requested that the Agency rely upon the data presented with the application. The pH range for the proposed product (4.60-7.2) is well within the pH range of the currently registered imidacloprid technical products (4.60-7.80) [MRID No. 477222-05].
- 7. In order to satisfy the discrepancy in the values of density, the registrant repeated the density analysis (using relative density) as opposed to bulk density and obtained the values of 1.51 g/ml, which is consistent with the density value of the cited product [MRID No. 422777-05].

DP BARCODE: D364944; FILE SYMBOL No.: 83558-GU; PRODUCT: Imidacloprid Technical

CONCLUSIONS

TRB has evaluated the additional product chemistry data submitted to support the registration application for proposed imidacloprid technical and has concluded that:

- 1. The data submitted corresponding to guideline reference 830.6313 (stability at room & elevated temperatures and to the metal and metal ions) and guideline reference 830.6314 (oxidation/reduction) are acceptable.
- 2. Based on the additional data provided for the guideline 830.7000 (pH) and the guideline 830.7300 (density), the Agency concludes that the proposed imidacloprid technical is substantially similar to the registered product with Reg. No. 264-755 from the product chemistry point of view, if the HED determines that the impurities in question are not of tox concern.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

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Certification with Respect to C	itation of Data	
Applicant's/Registrant's Name, Address, and Telephone Number Celsius Property BV, c/o MANA Inc., 4515 Falls of Neuse Rd, Ste 300, Raleigh, NC	27609	EPA Registration Number/File Symbol 83558-xx
Active Ingredient(s) and/or representative test compound(s) Imidacloprid		Date 4-1-09
General Use Pattem(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial non-food crop, Terrestrial food crop, greenhouse non-food crop	·	Product Name Imidacloprid Technical
NOTE: If your product is a 100% repackaging of another purchased EPA-registere submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement)		r all the same uses on your label, you do not need to
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies se	nt offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DATA SUPP	ORT(Check one m	ethod only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	the selective method of support (or cite-all option selective method), and have included with this form a list of data requirements (the Data Matrix form must be
SECTION II: GENERAL (OFFER TO PAY	
[Required if using the cite-all method or when using the cite-all option under the select	ive method to satisf	y one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to	the approval of this	application, to the extent required by FIFRA.
SECTION III: CERTI	FICATION	
I certify that this application for registration, this form for reregistration, or thi application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product, and (2) is requirements in effect on the date of approval of this application if the application soughuses.	addition, if the cite- (1) concem the pro s a type of data that ht the initial registra	all option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data tion of a product of identical or similar composition and
1 (vertify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, tha	at I am the original data submitter or that I have obtained
I certify that for each stilety cited in support of this registration or reregistratio submitter; (b) I have obtained the permission of the original data submitter to use the significant or the study; (d) the study is in the public literature; or (e) I offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c) amount and terms of compensation, if any, to be paid for the use of the study.	tudy in support of th I have notified in wri	is application, (c) all periods of eligibility for ting the company that submitted the study and have
I certify that in all instances where an offer of compensation is required, copi accordance with sections $3(c)(1)(F)$ and/or $3(c)(2)(B)$ of FIFRA are available and will be evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	e submitted to the A	Agency upon request. Should I fail to produce such
I certify that the statements I have made on this form and all attachme knowingly false or misleading statement may be punishable by fine or imprisor		
Signature / /	Date	Typed or Printed Name and Title
Signature Alume Til	4/1/2009	P. Leanne Pruett, Regulatory Product Manager

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send the form to this address.				~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	
	DATA	A MATRIX	^	er ex ex ex	ol ₁
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 1 of 14
Applicant's/Registrant's Name & Address Celsius Property B.V., Amsterdam (NL), c/o MANA, Inc., 4515 Falls of Neuse Rd., Ste 300, Raleigh, NC 27609		IC 27609	Product Imidacloprid Technical		
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550, 830.1600, 830.1620,	Product Chemistry 830 Series Group A	47344704	Celsius Property BV, Amsterdam (NL)	OWN	
830.1670, and 1700	•	Ħ	n	n	
830.1670	Discussion of Formation of Impurities	Enclosed	Celsius Property BV, Amsterdam (NL)	OWN	
830.1750	Preliminary Analysis	47357901	Celsius Property BV, Amsterdam (NL)	OWN	
830.1750	Preliminary Analysis	47357902	Celsius Property BV, Amsterdam (NL)	OWN	
	Product Chemistry 830 Series Group B			u .	
830.6302, 03, 04, .63 t3, .7000, .7300	Color, Physical State, Odor, Stability, pH, Density	Enclosed	Celsius Properly BV, Amsterdam (NL)	OWN	
830.6314	Oxidation / Reduction	Enclosed	Celsius Property BV, Amsterdam (NL)	OWN	
830.7000	5-Batch pH Report	Enclosed	Celsius Property BV, Amsterdam (NL)	OWN	
830.7000	5-Batch pH Report	Enclosed	Celsius Property BV, Amsterdam (NL)	OWN	
830.7000, 830.7300	pH & Density Discussion	Enclosed	Celsius Property BV, Amsterdam (NL)	OWN	
830.6317, .6320.7050, .7200, .7370,	Storage Stab., Corr, Char, UV/Vis, Melt. Pt., Dissoc Const.	47439801	Celsius Property BV, Amsterdam (NL)	OWN	
830.7550, .7840 and .7950	Partition Coeff, Solubility, and Vapor Pressure				
Signature P- Ham	in Dif		Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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ate 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 2 of t4
		Product Imidacloprid Technical			
ngredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements		Syngenta Crop Protection, Inc.	PAY	
			Attn: Regulatory Affairs		
			PO Box 18300		
			Greensboro, NC 27419		
			Nufarm Americas, Inc.	PAY	
			150 Harvester Drive, Suite 200		
			·Burr Ridge, IL 60527		
			Bayer Crop Science LP	PAY	
			2 T.W. Alexander Drive		
			Research Triangle Park, NC 27709		
			FMC Corp. Agricultural Products Group	PAY	
			Attn: Michael C. Zucker		
			1735 Market St., RM 1978		
			Philadelphia, PA 19103		
	7				
Signature	are M		Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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		DATA MATRIX			"
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 3 of 14
1		Product Imidacloprid Technical			
ngredient Imidacloprid					
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Chemtura Corporation; Attn: Crop Registration	PAY	
			199 Benson Road (2-5)		
			Middlebury, CT 06749		
			Bayer Environmental Science	PAY	
			A Business Group of Bayer CropScience LP		
			PO Box 12014		
			Research Triangle Park, NC 27709		
			The Scotts Company	PAY	
			14111 Scottslawn Road		
			Marysville, OH 43041		
			Cleary Chemicals, LLC	PAY	
			178 Ridge Road, Suite A		
			Dayton, NJ 08810		
	1 0				
Signature	Panae Pet		Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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	5 5 m S ₁				
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 4 of 14
		Product Imidacloprid Technical			
ngredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued.		PBI/Gordon Corp	PAY	
			PO Box 014090		
			Kansas City, MO 64101		
			Bayer Corp; Agricultural Division	PAY	
			PO Box 4913		
			Kansas City, MO 64120		
			Helena Chemical Co.	PAY	
			7664 Moore Rd.		
			Memphis, TN 38120		
			Gustafson LLC	PAY	
			PO Box 660065		
			Dallas, TX 75266		
			J. J. Mauget Co.	PAY	
			12733 Director's Loop		
			Woodbridge, VA 22192		
Signature A	Classe of		Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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	DA	TA MATRIX		. we we	`
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 5 of 14
		Product Imidacloprid Technical			
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued.		The Andersons Lawn Fertilizer Division	PAY	
			DBA/ Free Flow Fertilizer		
			PO Box 119		
			Maumee, OH 43537		
			Chemical Specialties Inc.	PAY	
			PO Box 1330		
			Harrisburg, NC 28075		
			Bayer Healthcare LLC; Animal Health Division	PAY	
			PO Box 390		
			Shawnee Mission, KS 66201		
			Mitsui Chemicals, Inc.	PAY	
			PO Box 5126		
			Valdosta, GA 31603		
Signature	Plane 1-9-	100	Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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		DATA MATRIX			
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 6 of 14
		Product Imidacloprid Technical			
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued.		Loveland Products, Inc.	PAY	
			Attn: Mark R. Trostle		
			PO Box 1286		
			Greeley, CO 80632		
			Lanxess Corporation	PAY	
			111 RIDC Park West Drive		
			Pittsburgh, PA 15275		
			Albaugh, Inc.	PAY	
			PO Box 2127		
			Valdosta, GA 31604		
			Aeroxon Inc.	PAY	
			2125 Center Ave., Suite 507		
			Fort Lee, NJ 07024		
Signature /	e care Int		Name and Title Leanne Pruett, Product Manager	•	Date 04/01/2009

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		DATA MATRIX			
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 7 of 14
Applicant's/Registrant's Name & Address Celsius Property B.V., Amsterdam (NL), c/o MANA, Inc, 4515 Falls of Neuse Rd, Suite 300, Raleigh, NC 27609		Product Imidacloprid Technical			
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Control Solutions, Inc.	PAY	
			5903 Genoa-Red Bluff		
			Pasadena, TX 77507		
			Nufarm Americas Inc.; AGT Division	PAY	
			150 Harvester Drive, Suite 200		
			Burr Ridge, IL 60527		
			Spray Drift Task Force	MEM	
			McKenna, Long & Aldridge LLP		
			1900 K Street, NW		
			Washington, DC 20006		
			Cheminova, Inc.	PAY	
			1600 Wilson Boulevard, Suite 700		
			Arlington, VA 22209		
Signature D. J. W.	an Dot	•	Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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	DA	TA MATRIX		H % H	
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 8 of 14
		Product Imidacloprid Technical			
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, continued		Mycogen Seeds c/o Dow Agrosciences LLC	PAY	
			9330 Zionsville Road		
			Indianapolis, IN 46268		
			Arbor Systems, Inc. D/B/A Arbor Systems	PAY	
			30856 Rocky Road		
			Greeley, CO 80631		
			Pet Logic, LLC	PAY	
***************************************			PO Box 540224		
			Omaha, NE 68130		
			Repar Corp	PAY	
			1050 Conn. Ave., NW, Suite 1000		
			Washington, DC 20036		
			United Phosphorus Inc.	PAY	
			630 Freedom Business Center, Suite 402		
			King of Prussia, PA 19406		
Signature D	anne Prof		Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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		DATA MATRIX		11.5	•
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page 9 of 14
		Product Imidacloprid Technical			
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, cont.		Nufarm, Inc.	PAY	
			150 Harvester Drive, Suite 200		
			Burr Ridge, IL 60527		
			Outdoor Residential Exposure Task Force	MEM	
			1350 I Street, NW		
			Washington, DC 20005		
			Agricultural Reentry Task Force	PAY	
			1350 i Street, N.W.		
			Washington, DC 20005		
			Bayer Advanced	PAY	
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			A Business Unit of Bayer CropScience LP		
			PO Box 12014		
			Research Triangle Park, NC 27709		
Signature A. Ha	nan AL	I	Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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DATA MATRIX					10
Date 4/1/2009			EPA Reg No./File Symbol 83558-xx		Page of 14
		Product Imidacloprid Technical			
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, cont.		Agrisel USA, Inc.	PAY	
			400 East Jane Street		
			Valdosta, GA 31601		
			Scimetrics, Ltd. Corp.	PAY	
			30856 Rocky Road		
			Greeley, CO 80631		
			Zelam Ltd.	PAY	
			17220 Westview Road		
			Lake Oswego, OR 97034		
			Rockwell Laboratories, Ltd.	PAY	
			D/B/A Rockwell Labs Ltd.		
			1512 Taney Street		
			North Kansas City, MO 64116		
Signature A	ine Pol		Name and Title Leanne Pruett, Product Manager	-	Date 04/01/2009

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DATA MATRIX					11	
Date 4/1/2009	te 4/1/2009 EPA Reg No./File Symbol 83558-xx				Page of 14	
		Product Imidacloprid Technical				
Ingredient Imidacloprid						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
	All other data requirements, cont.		Sapstain Industry Group (SIG)	PAY		
			1125 Trenton-Harbourton Rd.			
			Titusville, NJ 09560			
			Univar USA, Inc.	PAY		
			115 Obtuse Hill Rd.			
			Brookfield, CT 06804			
			Innovative Pest Control Products	PAY		
			PO Box 880216			
			Boca Raton, FL 33488			
			Arbor Jet	PAY		
			12510 Prosperity Drive, Suite 160			
			Silver Spring, MD 20904			
			Arch Treatment Technologies, Inc.	PAY		
			1955 Lake Park Drive			
			Smyrna, GA 30080			
Signature P. Ham	. 6.4	•	Name and Title Leanne Pruett, Product Manager		Date 04/01/2009	

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		DATA MATRIX		m m m m	12
Date 4/1/2009	EPA Reg No./File Symbol 83558-xx		Page of 14		
Applicant's/Registrant's Name & Address Celsius Property B.V., Amsterdam (NL), c/o MANA, inc., 4515 Falls of Neuse Rd, Suite 300, Raleigh, NC 27609			Product Imidacloprid Technical		
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
1000000	All other data requirements, cont.		FIFRA Endangered Species Task Force, LLC	PAY	
			c/o Harold Himmelman (Beveridge & Diamond)		
			1350 I Street, NW		
			Washington, DC 20005		
			Residential Exposure Joint Venture	PAY	
			900 17th Street, NW, Suite 300		
			Washington, DC 20006		
			Agricultural Handlers Exposure Task Force	мем	
			PO Box 509		
			Macon, MO 63552		
			GRO-PRO, LLC; D/B/A Etigra	PAY	
			4110 136th Street, Northwest		
**************************************			Gig Harbor, WA 98332		
Signature Policianie Policianie			Name and Title Leanne Pruett, Product Manager		Date 04/01/2009

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DATA MATRIX					13	
Date 4/1/2009 EPA			EPA Reg No./File Symbol 83558-xx		Page of 14	
Applicant's/Registrant's Name & Address Celsius Property B.V., Amsterdam (NL); c/o MANA, Inc., 4515 Falls of Neuse Rd, Suite 300, Raleigh, NC 27609			Product Imidacloprid Technical			
Ingredient Imidacloprid						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
	All other data requirements, cont.		Rotam Ltd	PAY		
			660 Newton-Yardley Rd., Suite t05			
			Newtown, PA t8940			
			Etigra LLC	PAY		
			4110 136th St, NW			
			Gig Harbor, WA 98332			
			Ensystex III, Inc.	PAY		
			4110 136th St., NW			
			Gig Harbor, WA 98332			
			Rotam Agrochemical Company Limited	PAY		
			660 Newton-Yardley Rd., Suite 105			
			Newton, PA 18940			
			Sharda USA LLC	PAY		
			7460 Lancaster Pike, Suite 9			
			Hockessin, DE 19707			
Signature f. Heave of			Name and Title Leanne Pruett, Product Manager	•	Date 04/01/2009	

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Form Approved OMB No. 2070-0060



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		DATA MATRIX		The second second	14
Date 4/1/2009	EPA Reg No./File Symbol 83558-xx			Page of 14	
		Product Imidacloprid Technical			
Ingredient Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other data requirements, cont.		Amtide, LLC	PAY	
			21 Hubble		111111111111111111111111111111111111111
			Irvine, CA 92618		
			Ensystex IV, Inc.	PAY	
			4110 136th St, NW		
			Gig Harbor, WA 98332		
			Dalian Chemphy Chemicals Co., Ltd.	PAY	
			1150 18th Street, NW, Suite 1000		
			Washington, DC 20036		
			Generic Endangered Species Task Force	МЕМ	
			4110 136th Street, Northwest		
			Gig Harbor, WA 98332		
			Max-Aba LLC	PAY	
			PO Box 640		
			Hockessin, DE 19707		
Signature P	Political Name and Title Leanne Pruett, Product Manager		Date 04/01/2009		

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Pages 78-94 * Claimed confidential by submitter*

Please read instructions on reverse before completing form.	Form Approved, UMB No. 20	970-0060 Print Form
Environmental Protection Washington, DC 20460	Agency X Registra Amendr	
Application	for Pesticide - Section I	•
1. Company/Product Number 83558-k/k GU	2. EPA Product Manager Venus Eagle	3. Proposed Classification
4. Company/Product (Name) Imidacloprid Technical	PM # 1	X None Restricted
5. Name and Address of Applicant (Include ZIP Code) Celsius Property, BV (neuhasen A Rhf Branch) c/o MANA, 4515 Falls of Neuse Rd, Suite 300 Raleigh, NC 27609 Check If this is a new address	6. Expedited Review. In accorda (b)(i), my product is similar or ident to: EPA Reg. No. 264-755 Em. dackgrid Product Name Techny ical Section - II Insecticide	
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For section in Application to register a new product. Fee Category: R310 Fee Due: \$4578.00	Final printed lebels in response Agency letter dated "Me Too" Application. Other - Explain below.) to
The PRIA fee has been paid on-line at www.pay.gov. A copy E-mail: [pruett@manainc.com]		Ħ
	Section - III	
Yes X No * Certification must be submitted Yes X No If "Yes" Unit Packaging wgt. container	Water Soluble Packaging Yes X No F "Yes" Package wgt Container S. Location of Lab	Metal Plactic Glase Paper Other (Specify)
3. Location of Net Contents Information X Label Container 6. Menner in Which Label is Affixed to Product Lithograp Paper glu Stenoiled	On Label On Label Other self-adhesive	
	Section - IV	
1. Contact Point (Complete items directly below for identification of	f individual to be contacted, if necessary, to pr	ocess this application.)
Name Pruett Tit	i e gulatory Product Manage	Telephone No. (Include Area Code) 919-256-9323
Certificatio certify that the statements I have made on this form and all acknowledge that any knowingly false or misleading statem both under applicable law., 2. Signature 3.	attachments thereto are true, accurate and cor	

Regulatory Product Manager

5. Date

April 2, 2008

EPA Form 8570-1 (Rev. 8-94) Previous editions era obsolete.

4. Typed Name

P. Leanne Pruett

White - EPA File Copy |original)



April 1, 2009

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504p)
U. S. Environmental Protection Agency
277 S. Crystal Drive, Room S-4900
Arlington, VA 22202

ATTN: Venus Eagle, PM #1
Registration Division

RE: Application to register a new product containing a currently registered active ingredient

Imidacloprid Technical - EPA Reg. No. 83558-XX; Me-Too Registration

Fee for Service – R310 – 6 month review process; \$4578.00

Dear Venus:

Makhteshim Agan of North America, Inc., as agent for Celsius Property BV (Neuhausen A Rhf Branch) is applying for registration of the above-referenced product. We are using the cite-all method of data support.

In support of this application, please find enclosed:

- PRIA Payment Confirmation
- Application for Pesticide Registration (EPA Form 8570-1)
- Confidential Statement of Formula (EPA form 8570-4) (2 copies)
- Certification with respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35) (1 copy each Public and EPA file copies)
- Transmittal Document
- Product Specific Chemistry Data, as outlined in Transmittal Document (3 copies each)
- CD containing references in support of Volume 1 of the submission (no MRID is needed; references are for information/reference purposes only)
- One (1) copy of draft labeling
- One (1) electronic copy of the draft labeling
- One (1) certification with respect to label integrity
- Copy of slides from last month's Imidacloprid Pre-Submission meeting with Celsius, EPA

As you know, Celsius previously submitted an application for registration for Imidacloprid Technical (EPA File Symbol 83558-RN, submitted 2-7-2008). This product was not considered substantially similar to the product we chose to 'me-too', so the application was withdrawn on August 26, 2008.



Manufacturing process information may be entitled to confidential treatment

U. S. EPA Venus Eagle, PM #1 April 1, 2009 Page 2 of 2

The reasons our initial registration was found not substantially similar were because of physical / chemical properties (pH and density) and because of the impurity profile.

For this new application for registration, we will be using the same sources of supply, and will be citing the preliminary analyses that were submitted with our February '08 application for registration. In order to address the issues that plagued our initial application, we have done extensive work addressing the pH, density and the impurities in question. You will find these studies, enclosed.

We are submitting this application as a 'me-too' application, claiming substantial similarity to three currently registered Imidacloprid technical products. First, we are claiming substantial similarity to Bayer Imidacloprid Technical Insecticide (EPA Reg. No. 264-755), because of impurity profile discussions contained in Vol 1. We are also claiming substantial similarity to Rotam, Ltd.'s Rotam Imidacloprid Technical (EPA Reg. No. 81598-5), because of the pH value of Rotam's product, as further discussed in Vol. 5. Finally, we are also claiming substantial similarity to Albaugh Inc.'s Imidacloprid Technical (EPA Reg. No. 42750-104).

In last month's pre-registration meeting, we requested that additional information on the impurities in the proposed product be sent to the Health Effects Division (HED) prior to review within the Technical Review Branch. To that end, we request that Volume 1 of this submission and the accompanying CD that contains references for data referenced in the report be forwarded to HED. We appreciate you accommodating this request and hope that the review can be accomplished within the standard PRIA timeframe.

As we discussed in last month's pre-registration meeting with you, we believe we have successfully addressed all problematic issues with this application and look forward to having the product registered. If you have any questions or concerns regarding this application, please let me know.

Best Regards,

P. Leanne Pruett

Authorized Agent - Celsius Property BV

Regulatory Product Manager - Makhteshim Agan of N. America, Inc.

(919) 256-9323

Ipruett@manainc.com



Transmittal Document

Imidacloprid Technical (EPA Reg. No. 83558-xx)

Submitter

Celsius Property B. V., Amsterdam (NL)
Neuhausen a. Rhf Branch
c/o Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300 Raleigh, NC 27609

Me-Too Application for Registration of a Technical Product Containing Imidacloprid

List of Submitted Studies:

Volume 1 of 6: Additional Information on the Dsicussion of the Formation of Impurities,

Supplement to MRID Number 47344704 (830.1670)

Volume 2 of 6: Imidacloprid Technical: Physico-chemical properties (color, physical state,

odor, pH, density) and stability to normal and elevated temperature.

metals and metal ions (OPPTS 830.6302, 830.6303, 830.6304, 830.6313,

830.7000, 830.7300)

Volume 3 of 6: Imidacloprid: Determination of pH Values in Five Technical Batches

(830.7000)

Volume 4 of 6: Imidacloprid: Determination of pH Values in Five Technical Batches

(830.7000)

Volume 5 of 6: Discussion of pH and Density Results (830,7000 and 830,7300)

Volume 6 of 6: Imidacloprid Technical Physical and Chemical Characteristics: Oxidation

/ Reduction (830.6314)

Submitted by: Company Name: Celsius Property B. V., Amsterdam (NL)

Neuhausen a. Rhf Branch.

Company Official:

P. Leanne Fruett Authorized Agent

Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

April 17, 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MANA, INC CELSIUS PROPERTY B.V., AMSTERDAM (NL) NEUHAUSEN A.RHF BRANCH 4515 FALLS OF NEUSE RD., SUITE 300 RALEIGH, NC 27609-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 06-APR-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Completion of 21-Day Content Screen

PM- _/_

EPA Reg. #(File Symbol) 8358-64

Decision # D 408528

Data package delivered to you on ________.

Jacket/Mini-jacket will be transferred to you today. (Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

Memorandum

Date:	4/1/09	
To:) m ol	_, Regulatory Manager
From:	Information Services	Branch, ITRMD
indication	our receipt of this data son that MRIDs for the osted to OPPIN.	
from th	e expect that it will be ne above date before to le in OPPIN.	approximately 5 days he study-level data is
•	you have any questions contact Teresa Downs (
This is a	a: fully accepted partially accepted rejected subm	



FW: Pay.Gov Payment Confirmation Leanne Pruett to: Teresa Downs

04/08/2009 03:14 PM

Dear Ms. Downs -

In an e-mail earlier today, you wrote:

"I could not find the confirmation of PRIA fee payment in your application package. Please email me a copy of the pay.gov receipt for this action, which has been assigned EPA file symbol 83558-GU."

Please see below for payment confirmation of PRIA fee.

Best Reggards,

Leanne Pruett

MANA

----Original Message----

From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]

Sent: Friday, April 03, 2009 3:26 PM

To: Leanne Pruett

Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Payment Summary

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 24VCNAH5 Agency Tracking ID: 74067978790

Account Holder Name: Anne Stout

Transaction Type: Sale

Billing Address: 4515 Falls of Neuse Rd.

Billing Address 2: Suite 300

City: Raleigh State/Province: NC Zip/Postal Code: 27609

Country: USA

Card Type: American Express Card Number: ********1002 Payment Amount: \$4,578.00

Transaction Date: Apr 3, 2009 3:26:07 PM

Decision Number:

Registration Number: 83558-



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

April 8, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-408528

EPA File Symbol or Registration Number: 83558-GU Product Name: IMIDACLOPRID TECHNICAL

EPA Receipt Date: 06-Apr-2009 EPA Company Number: 83558

Company Name: CELSIUS PROPERTY B.V., AMSTERDAM (NL)

LEANNE PRUETT MANA, INC CELSIUS PROPERTY B.V., AMSTERDAM (NL) NEUHAUSEN A.RHF BRANCH 4515 FALLS OF NEUSE RD., SUITE 300 RALEIGH, NC 27609-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

{848100g~

This package includes the following	for Division
New RegistrationAmendment	○ AD ○ BPPD ○ RD
 Studies? □ Fee Waiver? □ volpay % Reduction: 	Risk Mgr. 1
Receipt No. S-[848100
EPA File Symbol/Reg. No.	83558-GU
Pin-Punch Date:	4/6/2009
This item is NOT subject to	FFS action.
Action Code:	Parent/Child Decisions:
Requested: R-310	
Granted: R-310	
Amount Due: \$ 4578.00	
Tachnical and imperates only Sifterly	
M Inert Cleared for Intended Use	Uncleared Inert in Product
Reviewer: Venus Gagle	Date: 4809
Remarks:	
Needs to be sent to H	to for impurity clearence

21-Day Screen Completed by Contractor

21-Day Expires on 4-27-09

Jacket # 83558-60 MRID# 477222

21-day Content Screen: Passed/Failed

86-5 Review: Passed/Failed/NA

Transfer This Jacket to:

LINDA ARRINGTON

PRIA 2 – 21 Day Content Screen Review Worksheet

Expe	ay Screen Start Date: \(\(\sigma \) - \(\sigma \) - \(\sigma \) - \(\sigma \) \(\sig	9-09 ate	Fee F	'aid: Yo	es <u>√</u>	/
EPA F	Reg. Number: 83558-60 EPA Receipt Date:	1-6	- 0	9		
	Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & con including package type	nplete		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					
L	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-form) completed and signed (N/A if 100% repack)	·34) (Li	nk to	X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use onl					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link completed and signed (N/A if source is unregistered or applicant or technical)		,			X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes ×	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labelin (Electronic labels on CD are encouraged and guidance is availa http://www.epa.gov/pesticides/regulating/registering/submissions/index.h	able)(li	ink to	X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X	
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)		X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)		X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C. a) List study (or studies) not included with application		

Comments:

* All the studies have paned the PRN-86.5.

MRID 477222

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

^{*} N/A – Not Applicable

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



RE: Submission to EPA: Product Imidacloprid Technical

Leanne Pruett to: Aswathy Balan

Ce: Jennifer Yentel

04/17/2009 12:05 PM

Hi, Aswathy -

Attached, please find a PDF copy of the updated study. I've also faxed you a copy of this study. You can choose whichever method is easier for you to generate the reports - print off this PDF or copy the facsimile.

If you need any additional information, please let me know, and I'll send it right out to you.

Best Regards,

Leanne Pruett

MANA

----Original Message----

From: Balan. Aswathy@epamail.epa.gov [mailto:Balan. Aswathy@epamail.epa.gov]

Sent: Thursday, April 16, 2009 2:13 PM

To: Leanne Pruett

Cc: Jennifer Yentel; Nair.Sree@epamail.epa.gov

Subject: Submission to EPA: Product Imidacloprid Technical

Hi Ms. Pruett,

This is a follow-up email regarding your submission in support of the application for registration of the product Imidacloprid Technical (EPA Reg No: 83558-GU). We have found the following deficiency regarding your submission. In Volume 5: Discussion of pH and Density Results, you have provided a No Claim of Confidentiality Statement. But this statement is being contradicted by the markings 'Confidential Appendix' on the pages 18-35 of the study.>

You can either provide a new claim of confidentiality statement with cross references specifying those pages as a confidential attachment to the study or you can insert a new statement to the existing No Claim of Confidentiality statement like ' The above statement supercedes all other statements of confidentiality that may occur elsewhere in this report'.

You can send the revised pages either by fax to 703-305-5060/ Attn: Aswathy Balan or email it to balan.aswathy@epa.gov.

Thanks,

Aswathy Balan Contractor to EPA 2777 S. Crystal Drive, Arlington, VA 22202 Ph: 703-347-8787



20090417 Updated pH and Density Report.pdf

